

### **REMARKS**

Applicants and Applicants' attorney express appreciation to Examiner Alton Pryor for the courtesies handling of the recent Examiner Interview held December 3, 2008. Reconsideration and allowance for the above-identified application are now respectfully requested in view of the foregoing amendments and the following remarks. Claims 41-42, 44-48, 50-87 and 91-93 are pending, wherein claims 41, 45, 59, 65, 72, 77, 81 and 86 have been amended and new claim 93 was added. No claims cancelled by the amendment.

As discussed and agreed to during the Examiner Interview, McLaughlin does not disclose or suggest a non-abrasive dental bleaching composition that includes a dental bleaching agent, potassium nitrate, and a non-abrasive carrier. Instead, the sole example composition of McLaughlin that includes hydrogen peroxide and potassium nitrate also includes 83.5% of a "paste carrier" (col. 7, lines 7-14). Claims 41-42, 44-48, 50-64, 69, 72-80, 86-87, 91 and 93 are patentable over McLaughlin because they claim non-abrasive compositions that include a non-abrasive gel carrier.

Claims 65-71, 81-85 and 92 alternatively claim dental bleaching compositions that include about 0.5% by weight potassium nitrate. McLaughlin does not disclose or suggest the use of about 0.5% potassium nitrate. The general teaching regarding the optional use of potassium nitrate does not disclose any particular amount (col. 4, lines 9-11). In the sole example embodiment in McLaughlin that includes a bleaching agent and potassium nitrate, the potassium nitrate is included in an amount of 1%. As shown in the Comparative Study, dental bleaching compositions that include 0.5% potassium nitrate were found to provide the best reduction in sensitivity. There was no teaching, suggestion, motivation or other reason why one of skill in the art would have modified Example 4 of McLaughlin to include about 0.5% potassium nitrate rather than the amount actually included. For this reason, Applicants submit that claims 65-71, 81-85 and 92 are unobvious over McLaughlin. Accordingly, all of the claims as now presented are patentable and unobvious over McLaughlin. Applicants therefore respectfully request withdrawal of all remaining prior art rejections.

With respect to the last remaining obviousness-type double patenting rejection over U.S. Patent No. 6,306,370, Applicants note that they previously appealed this same rejection but never received a Board decision before the Examiner reopened prosecution. Applicants therefore request the Examiner to inquire into whether it is procedurally permissible for an

Examiner to repeat the same rejection taken on appeal when reopening prosecution without a Board decision on the merits. If this were possible one wonders how an applicant could ever take an issue on appeal and receive a Board decision without an examiner simply reopening prosecution and making the same rejection over and over to prevent the issue from reaching the Board.

Notwithstanding the foregoing, and in an effort to advance prosecution and avoid having to take any further appeals to the Board, Applicants agreed during the Examiner Interview to narrow the claims in order to overcome the obviousness-type double patenting rejection over the '370 patent. As set forth in this and previous office actions, the Examiner acknowledges that he is in agreement that the results of the Comparative Study show unexpected results for dental bleaching compositions that include about 0.01-2% potassium nitrate in combination with a dental bleaching agent. However, the Examiner believes that claims 3-30% by weight of a dental bleaching agent is not commensurate in scope with the test results, which tested dental bleaching compositions having bleaching agent concentrations of 10%, 10.5% and 15%. For this reason, Applicants agreed to narrow the claimed amount of dental bleaching agent.

As indicated by the Interview Summary, the Examiner indicates that claiming a range of about 10-20% by weight dental bleaching agent would be commensurate in scope with the unexpected results shown by the comparative study when used in combination with about 0.05-1% potassium nitrate. Accordingly, claims 44-45, 59-64, 77-80 and 91-92 were amended to define subject matter that was deemed to be patentable over the claims of the '370 patent. Accordingly, Applicants respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection of at least claims 44-45, 59-64, 77-80 and 91-92 over the '370 patent.

Applicants also respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection of the other claims over the '370 patent, which claim a bleaching agent in a range of about 10% to about 30% by weight. During the Examiner Interview, Applicants and the Examiner agreed that an important aspect of the unexpected results shown by the comparative study is the ability of the claimed quantity of potassium nitrate to substantially reduce tooth sensitivity that would otherwise be caused by the dental bleaching agent in the absence of the potassium nitrate. At very low quantities of bleaching agent one might expect there to be low tooth sensitivity simply because the amount of bleaching agent is low, not by virtue of the potassium nitrate. For example, a composition that only included 1% hydrogen

peroxide might cause little or no sensitivity, not because of the potassium nitrate but because of the relatively small amount of hydrogen peroxide. As a result, a claim that reads on such a composition may not be commensurate in scope with the unexpected results.

In order for a claimed concentration range of bleaching agent to be commensurate in scope with the unexpected results, such a range should at least read on compositions that include a sufficiently high quantity of bleaching agent that tooth sensitivity is likely in the absence of the claimed quantity of potassium nitrate. The Examiner acknowledges in the Office Action that compositions having 10% bleaching agent were actually tested and shown to provide unexpected results. Thus, a claimed concentration range in which the minimum quantity of bleaching agent is about 10% by weight is commensurate in scope with the test results. The Examiner also acknowledges in the Office Action that compositions having 15% bleaching agent and potassium nitrate were also described in an example in the Application as reducing tooth sensitivity. From this one can reasonably conclude that a bleaching agent range of about 10-15% is commensurate in scope with the unexpected results. In fact, the Examiner agreed that the bleaching agent range could safely be extended to about 10-20%.

The remaining issue is how much farther can this range be extended so as to cover concentrations that were not actually tested. According to relevant case law, “the unobviousness of a broader claimed range can, in certain instances, be proven by a narrower range of data. Often, one having ordinary skill in the art may be able to *ascertain a trend* in the exemplified data which would allow him to reasonably extend the probative value thereof. . . .” *In re Kollman*, 595 F.2d 48, 56 (CCPA 1979) (emphasis added); *see* MPEP 716.02(d) (8<sup>th</sup> ed. Rev. 2 May 2004). Applying the principles of *Kollman* to the present case, the Examiner has permitted Applicants to claim a narrowly tailored range for the potassium nitrate of about 0.05-1%. Indeed, the Office Action even acknowledges that the unexpected results were commensurate in scope with claiming the even broader range of about 0.01-2% potassium nitrate. Office Action, p. 7 (“Applicant also refers Examiner to examples 3-10 in instant specification, which suggest 0.01-2% potassium nitrate yields unexpected results. *Examiner is in agreement with Applicant’s results.*”). Nevertheless, Applicants agreed to narrow the claimed amount of potassium nitrate in order to advance prosecution and secure the allowance of at least some of the claims over the ‘370 patent.

When one considers the amount of potassium nitrate actually tested (0.5%) with the acceptable claim ranges (about 0.05-1% and about 0.01-2%) deemed to be commensurate in scope with the amount tested, one readily sees that claiming some amount over 0.5% is acceptable because it is consistent with the rule set forth in *Kollman*. From a mathematical standpoint, the upper range endpoint 1% is twice as much as 0.5% and 2% is four times greater than 0.5%. To maintain symmetry with this acceptable degree of range extension, one readily sees that 20% is twice as much as 10%, and 30% is twice as much as 15%. Bleaching compositions having 10% and 15% bleaching agent were both tested and described in the examples. Thus, an upper range limit of about 30% would appear to be justifiable according to this purely mathematical approach.

From a technical standpoint, an upper range limit of 30% is also reasonable. As stated above, there is a minimum level of bleaching agent that is required before one of skill in the art would expect to see substantial tooth sensitivity. The amount is probably less than 10% and greater than 3%, although some sensitivity in some people may be possible when using as little as 3% bleaching agent. However, quantities as low as 3% were not tested, and the application does not support a lower range endpoint between 3% and 10% (*e.g.*, 5%). Otherwise, Applicants would have claimed a lower endpoint of about 5% and argued that it is acceptably close to 10% in view of the fact that 10% and 15% were both tested and the mathematical difference between 5 and 10 is the same as the difference between 10 and 15. On the other hand, the Application provides support for claiming upper endpoints of 20%, 30% and 50%. The issue now is which upper endpoint is commensurate in scope with the unexpected test results.

According to *Kollman*, it is acceptable to claim a broader range in view of a narrow range of data if there is a discernable trend or other good reason to extend the data. Whereas claiming too low an amount of bleaching agent may result in compositions in which the small quantity of bleaching agent is itself responsible for the lack of sensitivity rather than the potassium nitrate, there is no upper limit beyond which sensitivity decreases. One of skill in the art would expect that a bleaching agent in *any* amount above 10% would still cause sensitivity. This is in fact the case, as evidenced by testing carried out for compositions having 15% bleaching agent. From this, one can see a clear trend. *Any* amount of bleaching agent above 10% will cause tooth sensitivity. As a result, the unexpected benefit of including low quantities of potassium nitrate should work in offsetting the effects of tooth sensitivity whenever sensitivity is caused by the bleaching agent. It is quite possible that the claimed amount of potassium nitrate would provide

at least some relief from tooth sensitivity for amounts of bleaching agent up to 50%. However, in an effort to be fair and reasonable, Applicants are not now advocating an upper limit as high as 50% but rather a more modest (and mathematically congruent) upper limit of about 30%. When the bleaching agent is included in a range about 10-30%, one of skill in the art would expect that (i) the dental bleaching agent will likely cause tooth sensitivity in the absence of the potassium nitrate and (ii) the potassium nitrate will provide some relief from tooth sensitivity. This is a reasonable interpretation of the data trends and supports the claims that require about 10-30% by weight bleaching agent as provided by *Kollman*. Applicants therefore submit that claims that require a bleaching agent in a range of about 10-30% and potassium nitrate in a range of about 0.05-1% are commensurate in scope with the test results and are therefore unobvious over the *claims* of the '370 patent.

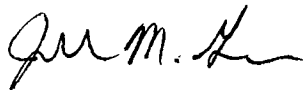
Finally, claims 86 and 87 alternatively claim the narrow range of bleaching agent found to be acceptable by the Examiner during the Examiner Interview, while new claim 93 recites the even narrower range of about 10-15%. Claims 86, 87 and 93 also claim the broader range of potassium nitrate (about 0.01-2%) which was deemed by the Examiner in the Office Action (p. 7) to be commensurate in scope with the unexpected results. Accordingly, Applicants submit that claims 86, 87 and 93 are unobvious over the *claims* of the '370 patent, which do not suggest this combination of bleaching agent and potassium nitrate ranges. New claim 93 is even more clearly patentable over the *claims* of the '370 patent because claim 93 claims a range of potassium nitrate (about 0.01-2%) that was deemed to be acceptable by the Examiner in combination with a range of bleaching agent whose lower and upper endpoints (*i.e.*, 10% and 15%) represent actual data points tested in the comparative study.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account No. 23-3178**: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178**.

Dated this 9<sup>th</sup> day of December 2008.

Respectfully submitted,



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